K122904

510(k) SUMMARY

NOV 15 2012

1. Date the summary was prepared: October 22, 2012

2. Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
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   Name of contact person: Joe Shia
   LSI International Inc.
   504 East Diamond Ave.,
   Suite F Gaithersburg, MD 20877
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3. Name of the device

   Common or usual name: Multi-Drug Urine Test Cup
   Multi-Drug Urine Test Panel
   Trade or proprietary name: Wondfo Multi-Drug Urine Test Cup
   Wondfo Multi-Drug Urine Test Panel

Classification: All are Class II medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	Classification	Regulation Section	Panel
DKZ Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
LDJ Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
DIO Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
LAF Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
DJR Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
LAF Methylenedioxymethamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
DJG Morphine	II	21 CFR § 862.3650, Morphine Test System	Toxicology (91)
LFG Notriptyline	II	21 CFR § 862.3910, Tricyclic antidepressant drug test system	Toxicology (91)
JXM Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
DJG Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
LCM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
DIS Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)

4. Description of the device:

Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Phencyclidine, Notriptyline and Oxycodone in human urine samples. Wondfo Multi-Drug devices detect each of analytes on different strips.

A positive urine sample will not generate a colored-line for the specific drug tested in the designated region. A negative urine specimen or a urine sample containing Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Phencyclidine, Notriptyline and Oxycodone at the concentration below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a test control, a color line will always appear at the control region.

5. Intended use of the device:

Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Phencyclidine, Notriptyline and Oxycodone in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine(AMP)	1000 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
Cannabinoids (THC)	50 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP)	300 ng/mL
Methadone (MTD)	300 ng/mL
Phencyclidine (PCP)	25 ng/mL
Notriptyline (TCA)	1000 ng/mL
Oxycodone (OXY)	100 ng/mL

Configuration of the Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel can consist of any combination of the above listed drug analytes.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

The test will yield preliminary positive results when prescription drugs Nortriptyline, Oxazepam, Oxycodone and Secobarbital are ingested, even at or above therapeutic doses. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

6. Comparison to the predicate device

Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel are a "modified" product format derived from the previously FDA-cleared Wondfo single DOA Tests. A summary comparison of features of the Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel and the predicate devices is provided in the following Table

Item	New Devices	Predicate devices (K112071)
Indication(s) for use	For the qualitative determination of Amphetamine (AMP), Secobarbital (BAR), Oxazepam (BZO), Cocaine (COC), Cannabinoids (THC), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA),	For the qualitative determination of Cocaine (COC), or Methamphetamine (MET), in human urine. The configurations of the Predicate devices are

	Morphine (MOP), Methadone (MTD), Phencyclidine (PCP), Notriptyline (TCA), and/or Oxycodone(OXY) in human urine. The configurations of the New Devices are available in any combination of the above tests.	only available in single drug test.
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type Of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Amphetamine (AMP): 1,000 ng/ml Secobarbital(BAR): 300 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml Cannabinoids (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Methylenedioxymethamphetamine (MDMA): 500 ng/ml Morphine (MOP): 300 ng/ml Methadone (MTD): 300 ng/ml Phencyclidine (PCP): 25 ng/ml Notriptyline (TCA):1,000 ng/ml Oxycodone(OXY) : 100 ng/ml	Same
Configurations	Cup, dip card	Same
Intended Use	OTC Use & Prescription Use	Same

Wondfo Multi-Drug Urine Test Cup is a multi-drug test that offers any combination from 2 to 12 drugs of abuse tests while the predicate devices are single-drug test. And the Wondfo Multi-Drug Urine Test Panel is the same as the test dip card format of the predicate devices except that the Wondfo Multi-Drug Urine Test Panel is a multi-drug test that offers any combination from 2 to 12 drugs of abuse tests while the predicate devices are single-drug test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 15, 2012

Guangzhou Wondfo Biotech Co., Ltd.
c/o Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878

Re: k122904
Trade/Device Name: Wondfo Multi-Drug Urine Test Cup
Wondfo Multi-Drug Urine Test Panel
Regulation Number: 21 CFR § 862.3250
Regulation Name: Cocaine and cocaine metabolite test system.
Regulatory Class: Class II
Product Code: DIO, DKZ, LDJ, LAF, DJR, DJG, LFG, JXM, LCM, DIS
Dated: October 22, 2012
Received: October 25, 2012

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122904

Device Name: Wondfo Multi-Drug Urine Test Cup

Indications for Use:
Wondfo Multi-Drug Urine Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Phencyclidine, Notriptyline and Oxycodone in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine(AMP)	1000 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
Cannabinoids (THC)	50 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP)	300 ng/mL
Methadone (MTD)	300 ng/mL
Phencyclidine (PCP)	25 ng/mL
Notriptyline (TCA)	1000 ng/mL
Oxycodone (OXY)	100 ng/mL

Configuration of the Wondfo Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K122904

The test will yield preliminary positive results when prescription drugs Notriptyline, Oxazepam, Oxycodone and Secobarbital are ingested, even at or above therapeutic doses. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

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510(k) K122904

Indications for Use

510(k) Number (if known): k122904

Device Name: Wondfo Multi-Drug Urine Test Panel

Indications for Use:
Wondfo Multi-Drug Urine Test Panel is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Phencyclidine, Notriptyline and Oxycodone in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine(AMP)	1000 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
Cannabinoids (THC)	50 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP)	300 ng/mL
Methadone (MTD)	300 ng/mL
Phencyclidine (PCP)	25 ng/mL
Notriptyline (TCA)	1000 ng/mL
Oxycodone (OXY)	100 ng/mL

Configuration of the Wondfo Multi-Drug Urine Test Panel can consist of any combination of the above listed drug analytes.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

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The test will yield preliminary positive results when prescription drugs Notriptyline, Oxazepam, Oxycodone and Secobarbital are ingested, even at or above therapeutic doses. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

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